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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,911	12/18/2001	Kit Yeng Lim	SBI-100	4817

7590

02/24/2004

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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 02/24/2004

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,911

Applicant(s)

LIM ET AL. *cl*

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/25/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

Specification

The attempt to incorporate subject matter into this application by reference to US Patent No. 5,290,763 is improper because mere reference to another patent is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. If an application incorporates essential material by reference to a U.S. patent, a copy of the referenced patent must be provided along with an indication of where the subject matter being incorporated by reference may be found ((See MPEP 608.01 (p))).

The amendment filed on November 25, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: "use of the apparatus or plug avoids fusion of the vertebrae adjacent to the defective annulus (claims 34 and 36)."

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claim 8 is objected to because it is an improper Omnibus-type claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, namely "avoids fusion of the vertebrae adjacent to the defective annulus," that was not described in the

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specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4, 6, 9-11, 13-14, 16, 18-20, 22-25, 29 and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Michelson (US 6,537,320).

Michelson discloses an implant or plug 20 made of a bioresorbable or “biodegradable” material such as polylactone (“polymer”) having a hollow portion or “bore” 42 containing bone growth inducing or promoting material and retaining members or “ridges” 36, 36’ on its outer surface wherein the plug is sealed at one end by a cap or “sealing member” 46 having a slot to engage a driver or tool for inserting and rotating implant 20 into disc space (Figures 1, 2A, and 2E, col. 11, lines 16-26, col. 12, lines 30-51 and col. 13, lines 24-60).

Michelson also discloses a plurality of openings or “apertures” 38, 38’ on the upper and lower walls 30, 30’, passing through the body and in communication with bore 42 (col. 12, lines 62-67 and col. 13, lines 1-23.)

The method steps of claims 19-20, 22-25, 29 and 30-33 are inherently performed during normal use of the Michelson implant for the purpose of sealing an intervertebral defect (Figure 3A, col. 18, lines 51-67 and col. 19, lines 1-31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 7-8, 12, 15, 17, 21, 26-28, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of Boyce et al. (US 6,294,187).

Regarding claims 5, 15 and 26, Michelson does not disclose specific types of biodegradable polymers.

Boyce et al. teach biodegradable polymers such as polylactic-co-glycolic acid, polycaprolactone, polycyanoacrylates etc. (col. 8, lines 23-40).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have made the Michelson implant of a biodegradable polymer, as taught by Boyce et al. to make the Michelson implant biodegradable.

The method steps of claim 26 are performed during normal use of the Michelson-Boyce et al. implant for sealing an intervertebral defect.

Regarding claims 7-8, 12, 17, 21, 27 and 28, Michelson does not disclose specific types of bone growth materials.

Boyce et al. teach the use of bioactive substances such as antibiotics, living cells, peptides, growth factors such as TGF-beta, bone morphogenetic proteins (BMPs), angiogenic agents etc. (col. 9, lines 31-67) in an implant.

Further, regarding claims 35 and 37, Boyce et al. teach shaping an osteoimplant to assume a determined configuration to custom fit a bone repair site with precision (col. 14, lines 6-50).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the bioactive substances taught by Boyce et al. in the Michelson implant to promote bone growth and to have shaped the Michelson implant to custom fit a repair site.

The method steps of claims 21, 27, 28, 35 and 37 are performed during normal use of the Michelson-Boyce et al. implant for sealing an intervertebral defect.

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Response to Arguments

Applicants' arguments submitted under "REMARKS" in Paper No. 8, filed on November 25, 2003, have been fully considered but are not persuasive.

Regarding Applicants' arguments with respect to claims 1-4, 6, 9-11, 13-16, 18-20, 22-25 and 29-33, that Michelson does not disclose "the very different function and operation of Applicants' device," it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. *Ex parte Marsham*, 2 USPQ2d 1647 (1987).

Further, the Examiner respectfully disagrees with Applicants' statement that the plug of the present invention avoids growth across the intervertebral space. Applicants' attention is directed to Page 8, lines 5-8 of the Specification of the instant application, wherein it is clearly stated that "the plug is integrated with surrounding tissues." It is the Examiner's position that "surrounding tissues" may include vertebral endplates.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

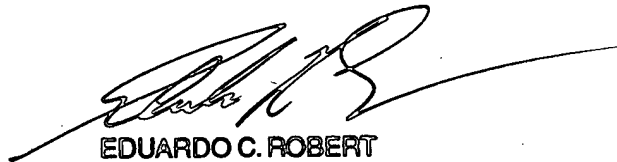
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Anuradha Ramana*
2/20/04


EDUARDO C. ROBERT
PRIMARY EXAMINER